

NATIONAL AQUACULTURE COUNCIL

A DIVISION OF
NATIONAL FISHERIES INSTITUTE



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August 26, 1997

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr.
Rm. 1-23
Rockville, MD 20857

0002 '97 SEP 19 12:54

Dear Sirs or Mesdames:

This letter is to provide the National Aquaculture Council's comments on the Food and Drug Administrations Request on development of options to encourage animal drug approvals for minor species and for minor uses (Docket No. 97N-0217) as published in the Federal Register June 23, 1997, Vol. 62 No. 120.

The National Aquaculture Council (NAC) is a division of the National Fisheries Institute and represents growers and processors of aquacultured products. The NAC wishes to compliment the Center for Veterinary Medicine for developing these questions for comment. This subject is vitally important to aquaculture since we are limited in the number of approved drugs available to treat our animals. If less restrictive standards for target animal safety can be found, we would support them. Regarding human food safety standards, we prefer these to remain as currently required. Food safety cannot be compromised.

We would suggest that different species be treated on a case-by-case basis except where species fall into one biological family. We would strongly urge that certain non-food fish designations (i.e. brood stock fish) be included in any future rule making.

Labeling differences would serve no useful purpose. Depending on how the standards were modified, we don't believe doses and withdrawal times would change much. We would support conditional approvals in appropriate situations and post-market surveillance. If post-market surveillance is used, we see no need for conditional labeling.

We fully support and encourage the agency to accept foreign reviews and approvals of new animal drugs. Data from any source, as long as it is scientifically sound, should be used to speed the approval process. Review of drug approval should remain with the agency using, where appropriate, expert panels or compendia for support.

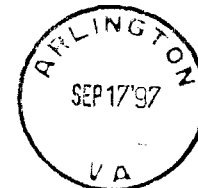
Every attempt should be made to speed up the INAD process continuing the use of field

97N-0217

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